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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/590,531

Filing Date: August 24, 2006

Appellant(s): KURIGER ET AL.

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John C Gatz  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 7/14/2010 appealing from the Office action  
mailed 5/25/2010.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1-7 and 10-35 are pending

Claims 1-7 and 10-35 are rejected

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

5,951,492	Douglas et al.	9-1999
2003/0171696	Dosmann	9-2003
2004/0127818	Roe et al.	7-2004

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-7 and 10-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas (US 5,951,492 referenced in previous action) in view of Dosmann (US 2003/0171696) and Roe et al (US 2004/0127818).

Douglas discloses an apparatus for lancing the skin of a test subject and collecting a body fluid sample from the lanced site comprising: A body (element 26) having an open end (see figure 1); a disposable element comprising a lancing needle for piercing the skin and a capillary tube for collecting the body fluid from the lancing site

(column 5, lines 36-43); a lancing mechanism for coupled to the needle adapted to move the lancet between a retracted position and a lancing position (column 5, lines 25-35); a mechanism for moving the capillary tube toward the lancing site for collecting a body fluid (column 5, lines 59-67); an outer end cap (element 24) having a first end couple to the open end of the body and a second end for contacting the skin of the subject, the outer end cap having an aperture that the tip of the lancet enters when in the lancing position, and a wall extending between the first and second end (column 5, lines 44-58; figures 1 and 2); and an inner end cap (element 66) disposed within the outer end cap having a first end couple to the body and a second end forming a second aperture that the lancet enters when lancing, the second end adapted to contact the skin of the test subject when in the collecting position, the wall of the outer end cap extending farther towards the skin than the inner end cap during lancing such that the skin of the subject is drawn inside the outer end cap and contacts the inner end cap (see figures 5 and 6).

However, Douglas does not disclose a hollow lancet for lancing and collecting the fluid sample wherein the interior of the hollow lancet forms a channel for moving the fluid sample from the tip to the reaction area; that the lancing mechanism provides for a collecting position; or that the outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection..

Dosmann teaches an optical format for lancing the skin for collecting a body fluid sample from the lanced site comprising a hollow lancet (element 10) having a tip adapted to puncture skin and collect body fluid (paragraphs [0003]-[0004]; figures 1 and

2); the interior of the hollow lancet forming a channel (element 13) for moving a fluid sample from the tip to a reaction area (paragraph [0014]). The body fluid is drawn through the channel using capillary action or vacuum assisted capillary action (paragraph [0014]). Furthermore this optical format and integrated lance includes a viewing window to allow optical analysis of the sample by transmission spectrometry by passing a beam of light through the lance viewing windows to a detector (paragraphs [0004] and [0014]). The lancet provides for significantly less pain, high probability of blood harvesting and improved overall test time by integrating the lance, harvest and analysis operations (abstract).

Roe teaches a tip design comprising an outer end cap for contacting the skin (element 46) and an inner end cap (element 82) disposed within the outer end cap wherein the outer end cap and the inner end cap remain in contact with the skin in the lancing position in order to assist in sample formation and collection (see figure 2, both end caps are in contact with the skin during the lancing position).

Regarding claims 1-7 and 10-35; it would have been obvious to one of ordinary skill at the time of the invention to substitute Douglas' disposable elements comprising separate needle and capillary tube connected to a test element with Dosmann's singular hollow lancet for lancing the skin and collecting fluid through the interior of the lancet in order to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Douglas' end caps to both remain in contact

with the skin during the lancing position as taught by Roe to assist in sample formation and collection.

Further regarding claims 1-7 and 10-35; Douglas teaches that the capillary tube is movable to a collecting position in order to collect the body fluid from the lancing area. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Douglas' lancing mechanism to include a collecting position in order to draw the fluid into the channel formed in the hollow lancet of a Douglas/Dosmann/Roe combination.

Further regarding claims 2, 3, 10 and 29-32; Dosmann discloses the lancet defined by a square, fused silica capillary tube (paragraph [0010]).

Further regarding claim 4-6; Dosmann discloses the use of a vacuum around the lancing area to enhance blood flow (paragraph [0004]). It would have been obvious to one of ordinary skill in the art at the time of the invention that a vacuum used in the Douglas/Dosmann/Roe combination apparatus when the outer end cap is in contact with the skin would evacuate the air from the inner and outer ends caps and thusly create a vacuum that would position the skin of the test subject against the second end of the inner end cap.

Further regarding claims 5 and 6; it would have been obvious to one of ordinary skill in the art at the time of the invention to use known methods of applying a vacuum in blood collection devices including use of a diaphragm or bellows.

In regards to claim 7; Dosmann discloses using a light source for illuminating the reaction of the reagent and analyte in the fluid sample and a light detector for detecting light transmission through the reaction (paragraph [0014]).

Regarding claim 11; it would have been obvious to one of ordinary skill in the art at the time of the invention to have the retracted and collecting positions of a Douglas/Dosmann/Roe combination be substantially the same in order to simplify the lancing mechanism so that it only has two positions instead of three (since the collecting and retracted position would be the same).

Further regarding claims 12-34; the method as claimed would define the obvious use of a Douglas/Dosmann/Roe combination in view of Dosmann's disclosure on the method of optically analyzing a body fluid collected from a puncture site (paragraph [0014]) and Douglas' disclosure of how the lancing body and mechanism works.

In regards to claim 18 and 28; it would have been obvious to one of ordinary skill of optical analysis to determine the start time of a colorimetric reaction based on the light transmitted through the lancet.

Further regarding claim 35; Douglas shows that the inner end cap does not extend beyond the outer end cap in the retracted, lancing and collecting positions (figures 1-6). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that the inner end cap remained entirely disposed within the outer end cap in all positions.

**(10) Response to Argument**

The applicant's arguments/remarks filed on 7/14/2010 have been fully considered but are non persuasive.

[Regarding claims 1-7 and 10-35]

The applicant argues that the rejection of the pending claims are improper for the following reason (1) Douglas explicitly teaches away from the Examiner's proposed modifications; (2) there is no teaching or suggestion to combine Douglas and Dosmann; and (3) the examiner's proposed modifications would change the principle of operation of Douglas. The examiner finds the arguments non persuasive.

The applicant argues that Douglas explicitly teaches away from the examiner's proposed modifications citing that Douglas explicitly states that the inner sleeve 66 is in contact with the skin only when the lancing is complete and the outer sleeve is retracted and thus a person of ordinary skill in the art upon reading Douglas would be led in a direction divergent from the examiner's proposed modification. The examiner finds this argument non persuasive because although Douglas discloses the outer sleeve is retracted so that the inner sleeve can contact the blood after lancing, the examiner contends that one of ordinary skill in the art would realize that allowing the inner sleeve to be in contact during lancing as taught by Roe would no hinder to change the operation of Douglas' blood sensing electrodes. The blood would still bead up and be detected by the electrodes regardless if the inner sleeve was in contact during the lancing operation or after the lancing operation, and thus the examiner contends that the modification proposed in the rejection does not teach away from Douglas' teachings.

The applicant argues that there is no teaching or suggestion to combine Douglas with Dosmann because Dosmann's hollow lancet is unmovable and thus has a single position while Douglas' disposable lancet is specifically designed to be movable to move between retracted and lancing positions; and further that Douglas is directed to a reusable lancing device while Dosmann is directed to a disposable lance. The examiner finds the arguments non persuasive as the examiner's proposed modification for the rejection calls for the substitution of Douglas' disposable lancet, capillary tube and test strip with Dosmann's disposable hollow optical format integrated lance which fulfills the functions of Douglas' disposable element. As such, Douglas teaches a lancing device which is designed to move the disposable elements between the retracted and lancing positions and as such would be capable of moving Dosmann's disposable integrated lancet between the retracted and lancing positions. Furthermore, the examiner contends that although Douglas does disclose a reusable lancing device, it is explicitly disclosed that the device is a housing designed to move disposables (the lance, capillary tube and test strips) between the retracted and lancing positions. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the disposable aspects of Douglas (lancet, capillary tube and test strip) with the disposable Dosmann lancet (hollow lancet used for lancing and withdrawing blood through capillary action) as simple substitution of one known element for another to yield predictable results, the predictable result being Douglas' reusable lancet device which uses Dosmann's disposable hollow lancets for lancing and collected bodily fluid.

Finally, the applicant argues that the examiner's modifications would change the principle of operation of Douglas saying that modifying Douglas such that sleeves 24 and 66 both remain in contact with the skin during the lancing position would eliminate Douglas's feature of expressing body fluid because the inner sleeve would press down on the patient's skin and eliminate the bulge of body tissue. The examiner disagrees with the applicant's assessment as Roe explicitly discloses in figures 2 and 3 showing that the outer sleeve still produces a droplet of body fluid by creating a bulge in the skin using the outer sleeve (see figure 3) while using the inner sleeve to contact the skin during lancing (figure 2).

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ADAM J EISEMAN/

Examiner, Art Unit 3736

10/14/2010

Conferees:

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

/Linda C Dvorak/

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